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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,402	07/30/2003	Patrice Flaherty	1066	9003

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01/09/2007

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/630,402	<b>Applicant(s)</b> FLAHERTY, PATRICE	
	<b>Examiner</b> Jeffrey G. Hoekstra	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 24-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 10/19/2006, amended claims 1, 7, 24, and 32 are acknowledged. The current rejections of the claims 1-11 and 24-32 are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Claim Objections***

2. Claim 32 is objected to because of the following informalities: the positive recitation of "a port tubing bifurcation" is structurally unclear. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Strittmatter (US 5,396,899).

5. For claim 7, Strittmatter discloses a multi-channel bodily-fluid handling device, comprising:

- a main tubing segment (11) for the passage of bodily fluids;

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- an indicator unit (25) and a syringe port (24) disposed in fluid communication with said main tubing segment and in a branched relationship to each other, wherein said indicator unit has a fluid volumeter (30);
- a clamp (20) operably engaging said main tubing segment for selectively blocking fluid; and
- an air-permeable liquid-impervious membrane (34) disposed in said indicator unit at a distal end (as best seen in Figures 6 and 7).

6. For claim 8, Strittmatter discloses a multi-channel bodily-fluid handling device, further comprising: a fluid volumeter (30) disposed in said indicator unit.

7. For claims 9 and 11, Strittmatter discloses a multi-channel bodily-fluid handling device wherein said indicator unit is disposed in removable fluid communication with said main tubing segment as best seen in Figures 5 and 6.

8. For claim 10, Strittmatter discloses a multi-channel bodily-fluid handling device wherein said fluid volumeter is a volumeter chamber (column 4 lines 24-41).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-6 and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strittmatter in view of Prager (US 4,257,416).

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11. For claims 1, 24 and 32, Strittmatter discloses a multi-channel bodily-fluid handling device, comprising:

- a main tubing segment (11) for the passage of bodily fluids;
- an indicator unit (25) and a syringe port (24) disposed in fluid communication with said main tubing segment via a syringe leg (as best seen in Figure 2) and in a branched relationship to each other, wherein said indicator unit has a fluid volumeter (30);
- a clamp (20) operably engaging said main tubing segment adapted to selectively block and unblock; and
- an air-permeable liquid-impervious membrane (34) disposed in said indicator unit at a distal end (as best seen in Figures 6 and 7); and
- wherein said fluid volumeter is disposed between said main tubing segment and said at least one air-permeable liquid-impervious membrane (as best seen in Figure 5 and 6).

12. For claims 2 and 4, Strittmatter discloses a multi-channel bodily-fluid handling device, further comprising: a fluid volumeter (30) disposed in said indicator unit.

13. For claim 3 and 6, Strittmatter discloses a multi-channel bodily-fluid handling device wherein said indicator unit is disposed in removable fluid communication with said main tubing segment as best seen in Figures 5 and 6.

14. For claims 5 and 26, Strittmatter discloses a multi-channel bodily-fluid handling device wherein said fluid volumeter is a volumeter chamber (column 4 lines 24-41).

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15. For claim 25, Strittmatter discloses a multi-channel bodily-fluid handling device, further comprising: a connector (12) disposed in fluid communication with said main tubing segment and disposed in removable fluid communication with said indicator unit.

16. For claim 27, Strittmatter discloses a multi-channel bodily-fluid handling device, further comprising: a collector conduit (21) disposed in fluid communication with said main tubing segment via a collector tubing leg (as best seen in Figure 2) and disposed in fluid communication with said indicator unit.

17. For claim 28, Strittmatter discloses a multi-channel bodily-fluid handling device wherein said indicator unit comprises a volumeter conduit (19) disposed in fluid communication with said collection conduit and disposed in fluid communication with said volumeter conduit.

18. For claim 29, Strittmatter discloses a multi-channel bodily-fluid handling device, further comprising: a port (22) disposed between said collector and volumeter conduits.

19. For claim 30, Strittmatter discloses a multi-channel bodily-fluid handling device, further comprising: a syringe tubing (15) segment disposed in fluid communication with said main tubing segment and wherein said port (24) is disposed on said syringe tubing segment.

20. For claim 31, Strittmatter discloses a multi-channel bodily-fluid handling device, further comprising: a connector (13) disposed in said main tubing segment between said clamp and said indicator unit and said port.

21. Strittmatter discloses the claimed invention except for explicitly disclosing the indicator unit and syringe port in a branched relationship to each other and the main

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tubing segment. Prager teaches a main tubing segment (16), an indicator unit (a withdrawal bag attaching to element 40) (column 1 lines 1-22), and a spring port (36) all in a branched relationship (as best seen in Figure 1) and all with associated clamps (52, 54, 56, and 58) adapted to block and unblock fluid communication. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the multi-channel bodily-fluid handling device as taught by Strittmatter, with the branching taught by Prager for the purpose of increasing the efficacy of a multi-channel bodily-fluid handling device to disperse and withdrawal fluids in a variety of configurations.

### ***Response to Arguments***

22. Applicant's arguments with respect to claims 1-11 and 24-32 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

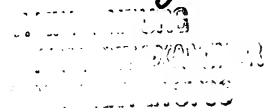
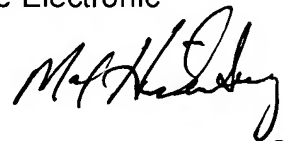
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JH

